K130373

BECKMAN COULTER

510(k) Summary
Navios™ Flow Cytometer System

1.0 Submitted By:

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SEP 18 2013

2.0 Date Submitted:

February 13, 2013

3.0 Device Name – Classification

Navios™ Flow Cytometer with Navios tetra software and Navios software (off-line software package) – Automated Differential Cell Counter, OYE (21 CFR § 864.5220)

Flow-Set™ Pro Fluorospheres – Automated Differential Cell Counter, PDX (21 CFR § 864.5220)

4.0 Predicate Devices:

Candidate	Predicate	Manufacturer	Docket Number
Navios Flow Cytometer with Navios tetra software and Navios software (off-line analysis software)	Cytomics FC 500 with tetraCXP software	Beckman Coulter, Inc.	K030828
Flow-Set Pro Fluorospheres	Flow-Set Fluorospheres	Beckman Coulter, Inc.	K944751

5.0 **Description:**

The Navios Flow Cytometer system is composed of the following components:

- Navios Flow Cytometer
- Navios tetra Software
- Navios Software (off-line analysis tool)
- Flow-Set Pro Fluorospheres
- CYTO-STAT tetraCHROME reagents
- COULTER IMMUNOPREP Reagent System
- TQ-Prep Workstation (Accessory for Sample Preparation)
- PrepPlus™ 2 Workstation (Accessory for Sample Preparation)

The Navios Flow Cytometer uses flow cytometric principles to determine qualitative and quantitative measurements of biological and physical properties of cells and other particles. These properties are measured when the cells pass through the laser beam(s) in single file.

The Navios tetra software is an optional locked algorithm application plug-in that is designed for the Navios flow cytometer. It provides automated analysis and results for tetraCHROME reagents; this application cannot be modified by the user.

The Navios Flow Cytometry System also offers an optional standalone offline software package, Navios software, which may be installed on an independent computer workstation for off-line analysis of listmode files generated by the Navios Flow Cytometer with tetraCHROME reagents and Navios tetra software according to the product labeling.

CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 reagent provides identification and enumeration of CD3+CD4+, CD3+CD8+, and CD3+ lymphocyte percentages and absolute counts in peripheral whole blood. CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 reagent provides identification and enumeration of CD3+, CD19+ and CD3-CD56+ lymphocyte percentages and absolute counts in peripheral whole blood.

Flow-Set Pro Fluorospheres is a suspension of fluorospheres with uniform and stable size and fluorescence intensity. The stability of these product parameters allows for the standardization of light scatter and fluorescence intensity instrument settings.

The COULTER ImmunoPrep Reagent System is comprised of 3 ready-to-use reagents: Reagent A lyses the red blood cells, Reagent B buffers the solution and stops the lysing process, and Reagent C fixes the cells. This reagent system provides a rapid, no-wash, standardized, whole blood lysing solution for sample to sample, and laboratory to laboratory reproducibility.

The Navios Flow Cytometer uses sample preparation devices as part of the overall workflow system. The COULTER TQ-Prep Workstation is used with the COULTER ImmunoPrep Reagent System to prepare leukocytes from whole blood for quantitative immunofluorescence measurements on flow cytometers. The COULTER PrepPlus 2 is a microprocessor-controlled pipetting and diluting system, designed for automating sample preparation or assay methods. It is capable of aspirating and dispensing liquid samples.

6.0 **Intended Use:**

Navios Flow Cytometer

The Navios Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping. It can be used in conjunction with the following monoclonal antibody reagents and software package:

- CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents. These reagents provide identification and enumeration of CD3+CD4+, CD3+CD8+, CD3+, CD19+ and CD3-CD56+ lymphocyte percentages and absolute counts in peripheral whole blood. Absolute counts may be determined by the Navios flow cytometer using Flow-Count Fluorospheres (single platform technology method) or separate hematology results (dual platform method). These reagents are indicated for use in the immunologic assessment of patients having or suspected of having immune deficiency.

- Navios tetra Software for automated analysis and results with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents.

Navios Software may be installed on an independent computer workstation for off-line analysis of listmode files generated by the Navios Flow Cytometer with the monoclonal antibody reagents and software package listed above. The off-line analysis must be performed in accordance with the product labeling.

Navios tetra Software

The Navios tetra Software is intended for use as an in vitro diagnostic device for immunophenotyping with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents on the Navios Flow Cytometer.

It provides automated analysis and results for the identification and enumeration of CD3+CD4+, CD3+CD8+, CD3+, CD19+ and CD3-CD56+ lymphocyte percentages and absolute counts in peripheral whole blood. Absolute counts may

be determined by the Navios flow cytometer using Flow-Count Fluorospheres (single platform technology method) or separate hematology results (dual platform method). It is indicated for use in the immunologic assessment of patients having or suspected of having immune deficiency.

Flow-Set Pro Fluorospheres

Flow-Set Pro Fluorospheres is a suspension of fluorescent microspheres used as an aid in standardizing forward scatter, side scatter, and fluorescence detectors (FL1-4) on the Cytomics FC 500 and Navios Flow Cytometers.

7.0 **Comparison to Predicates:**

Navios Flow Cytometer with Navios tetra Software and Navios Analysis Software

Attribute	FC 500 flow cytometer (Predicate)	Navios flow cytometer
Intended Use	FC 500 Flow Cytometer with tetraCXP software: The tetraCXP Software for Cytomics FC 500 flow cytometry systems and CYTO-STAT tetraCHROME™ CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME™ CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 Monoclonal Antibody Reagents combine four-color fluorescent monoclonal antibody reagents, quality control reagents, an optional absolute count reagent, and software for automated analysis of lymphocyte populations in whole blood using Cytomics FC 500 flow cytometry systems with CXP Software. The system with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 is intended "For In Vitro Diagnostic Use" and allows simultaneous identification and enumeration of total CD3+, total CD4+, total CD8+, dual CD3+/CD4+ and dual CD3+/CD8+ T lymphocyte population percentages and absolute counts. The system with CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5	Navios Flow Cytometer: The Navios Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping. It can be used in conjunction with the following monoclonal antibody reagents and software package: • CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents. These reagents provide identification and enumeration of CD3+CD4+, CD3+CD8+, CD3+, CD19+ and CD3-CD56+ lymphocyte percentages and absolute counts in peripheral whole blood. Absolute counts may be determined by the Navios flow cytometer using Flow-Count Fluorospheres (single platform technology method) or separate hematology results (dual platform method). These reagents are indicated for use in the immunologic assessment of patients having or suspected of having immune deficiency.

Attribute	FC 500 flow cytometer (Predicate)	Navios flow cytometer
	is intended "For In Vitro Diagnostic Use" and allows simultaneous identification and enumeration of total CD3+ (T), CD19+ (B), and CD3-/CD56+ (NK) lymphocyte population percentages and absolute counts. This reagent reflects the distribution of the three major subsets comprising the lymphocyte population upon which other lymphocyte enumeration studies are based and provides the total lymphocyte percentage.	• Navios tetra Software for automated analysis and results with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents. Navios Software may be installed on an independent computer workstation for off-line analysis of listmode files generated by the Navios Flow Cytometer with the monoclonal antibody reagents and software package listed above. The off-line analysis must be performed in accordance with the product labeling.
Device Classification and Product Code	864.5220, Automated Differential Cell Counter, GKZ	864.5220, Automated Differential Cell Counter, OYE
Optics	Free space delivery and collection of laser light	Same except collection also uses fiber optics
Electronics	200 KHz sampling Analog integrator circuitry w/ late stage ADC Yields ~1,500 events/sec	40 MHz sampling Digital integrator circuitry w/ early stage ADC Yields ~25,500 events/sec
Quality Control Techniques	• Daily Instrument Checks • Commercial Controls • Inter-laboratory Quality Assurance Program (IQAP)	Same

Attribute	FC 500 flow cytometer (Predicate)	Navios flow cytometer
Sample Introduction	• Automated presentation with Multi-tube Carousel Loader (MCL) from 32 test tube capacity carousel • Manual presentation into a tube location on MCL via tube access door	Same
Sample Analysis	• Principle of analysis – Flow cytometric • Detection hardware – Lasers, fluidics, optics, electronics • Sample analysis pathway • Manual gating of cellular populations by user or automated gating of cellular populations with algorithmic software	Same
Automated algorithm analysis for tetraCHROME reagents	tetraCXP software	Navios tetra software
Accessories	Optional software kits for analysis on off-line workstations	Same

Flow-Set Pro Fluorospheres

Attribute	Flow-Set Fluorospheres (Predicate)	Flow-Set Pro Fluorospheres
Intended Use	Flow-Set Fluorospheres are a suspension of Fluorospheres (fluorescent microspheres) used as an aid in optimizing a flow cytometer for quantitative analysis of human leukocytes.	Flow-Set Pro Fluorospheres is a suspension of fluorescent microspheres used as an aid in standardizing forward scatter, side scatter, and fluorescence detectors (FL1-4) on the Cytomics FC 500 and Navios Flow Cytometers.
Device Classification and Product Code	864.8625, Hematology Quality Control Mixture, JPK	864.5220, Automated Differential Cell Counter, PDX
Reagent Components	3.6 µm (nominal diameter) polystyrene fluorospheres suspended in an aqueous medium containing surfactants and preservatives at 1 x 10^6 fluorospheres/mL (nominal concentration)	Same except 3 µm (nominal diameter) polystyrene fluorospheres
Fluorescence Emission	Ranges from 525 nm to 700 nm when excited at 488 nm	Ranges from 515-800 nm when excited at 488 nm
Suspension solution	Aqueous medium containing surfactants and preservatives at 1 x 10^6 fluorospheres/mL (nominal concentration)	Same
Manufacturing Process	Polymerized in the presence of a single, broad spectrum dye.	Manufactured by loading a solution of three dyes into a polystyrene particle.
Bead Fluorochromes	Rubicene dye	Rubicene dye, IR-676 dye, Perylene dye
Laboratory instrument standardization	• Establishing Fluorescence and/or Light Scatter Target Ranges • Establishing Instrument HV/ Total Gain	Same

Attribute	Flow-Set Fluorospheres (Predicate)	Flow-Set Pro Fluorospheres
	Ranges • Daily Instrument Standardization	
Applicable Instruments	Cytomics FC 500 Epics XL/XL-MCL	Navios Cytomics FC 500
Sample Preparation	Must be thoroughly mixed prior to use. Samples in test tubes which stand for an extended period of time should be vortex mixed before use. No other sample preparation is necessary.	Same
Target Value Ranges	Procedure provided for user to establish target value ranges for each manually gated application. Additionally, target value ranges provided for algorithm-based IVD software applications such as tetraCXP for FC 500 flow cytometer	Same as Flow-Set with target value ranges provided for Navios tetra software
Final Product Form	Liquid, ready to use	Same
Open Vial Stability	65 days	Same
Closed Vial Stability	18 months	10 months

8.0 **Summary of Performance Data:**

Navios Flow Cytometer with Navios tetra Software and Navios Analysis Software

Study	Study Design	Study Results
Accuracy	Based on CLSI EP9-A2, Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition.	The Navios flow cytometer demonstrated comparable results to the predicate device with CYTO-STAT tetraCHROME Reagents (CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CD45-FITC/CD56-RD1/CD19/ECD/CD3-PC5).
Precision	1) Based on CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. 2) Whole Blood Repeatability	The Navios flow cytometer demonstrated acceptable results with CYTO-STAT tetraCHROME Reagents.
Linearity	1) Based on CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline. 2) Pairs of ImmunoBrite beads and Ultra Rainbow Calibration particles evaluated across the dynamic range of each detector.	The Navios flow cytometer demonstrated acceptable linearity results.
Assay and Instrument Carryover	Based on recommendations contained in CLSI H26-A2, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Guideline-Second Edition; Section 5.7 – Carryover	The Navios flow cytometer demonstrated acceptable carryover results.
Specimens	Specimens tested over the sample stability and prepared sample stability claims.	Acceptable sample and prepared sample stability results achieved.

Study	Study Design	Study Results
Reference Values	Based on CLSI C28-A3, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory, Approved Guideline – Third Edition	Reference intervals established.
Single vs. Dual Platform Absolute Counting Method Comparison	Based on CLSI EP15	Demonstrated comparable absolute count results from single and dual platform methods.
Laser Performance Characterization	Evaluated mean channel values for FS and fluorescence detectors measured for integral signal intensity variation and half peak coefficient of variation (HPCV).	Acceptable laser performance characterization results achieved.
Limits	Based on the CLSI EP17-A2 Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline	Established the Limit of Blank, Limit of Detection and Low Limit of Quantitation values for each tetraCHROME marker when tested on the Navios system
Manual Pipette vs. PrepPlus 2 Method Comparison	Based on CLSI EP15	Demonstrated comparable results are achieved when specimens are prepared using a manual pipette and PrepPlus 2 workstation.

Flow-Set Pro Fluorospheres

Study	Study Design	Study Results
Open and Closed Vial Stability	Evaluated open and closed vial stability of multiple lots of Flow-Set Pro Fluorospheres over the shelf life of the product on a Navios flow cytometer.	Flow-Set Pro Fluorospheres demonstrated acceptable results.
Analyte Value Assignment	Using iterative process, established target value ranges for Flow-Set Pro Fluorospheres with Navios tetra software.	Established process for generating target value ranges for Navios tetra software.
FC 500 Flow Cytometer Usage	Established target channel and ranges for Flow-Set Pro Fluorospheres on an FC 500 flow cytometer and used them for daily instrument standardization according to instructions provided in product labeling.	Demonstrated acceptable results with Flow-Set Pro Fluorospheres on an FC 500 flow cytometer.
Precision	Based on CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition.	Flow-Set Pro Fluorospheres demonstrated acceptable results.

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to products already in commercial distribution.

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 18, 2013

BECKMAN COULTER, INC.
C/O MS. NANCY NADLER
11800 S.W. 147 AVENUE
M/S 31-B06
MIAMI, FL 33196-2500

Re: K130373

Trade/Device Name:	Navios Flow Cytometer System
Regulation Number:	21 CFR 864.5220
Regulation Name:	Automated Differential Cell Counter
Regulatory Class:	Class II
Product Code:	OYE, PDX
Dated:	August 14, 2013
Received:	August 16, 2013

Dear Ms. Nadler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Reena Philip -S

for Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130373

Device Name
Navios™ Flow Cytometer

Indications for Use *(Describe)*

The Navios Flow Cytometer is intended for use as an in vitro diagnostic device for immunophenotyping. It can be used in conjunction with the following monoclonal antibody reagents and software package:

• CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents. These reagents provide identification and enumeration of CD3+CD4+, CD3+CD8+, CD3+, CD19+ and CD3-CD56+ lymphocyte percentages and absolute counts in peripheral whole blood. Absolute counts may be determined by the Navios flow cytometer using Flow-Count Fluorospheres (single platform technology method) or separate hematology results (dual platform method). These reagents are indicated for use in the immunologic assessment of patients having or suspected of having immune deficiency.
• Navios tetra Software for automated analysis and results with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents.

Navios Software may be installed on an independent computer workstation for off-line analysis of listmode files generated by the Navios Flow Cytometer with the monoclonal antibody reagents and software package listed above. The off-line analysis must be performed in accordance with the product labeling.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130373

Device Name
Navios™ tetra Sofware

Indications for Use *(Describe)*

The Navios tetra Software is intended for use as an in vitro diagnostic device for immunophenotyping with CYTO-STAT tetraCHROME CD45-FITC/CD4-RD1/CD8-ECD/CD3-PC5 and CYTO-STAT tetraCHROME CD45-FITC/CD56-RD1/CD19-ECD/CD3-PC5 monoclonal antibody reagents on the Navios Flow Cytometer.

It provides automated analysis and results for the identification and enumeration of CD3+CD4+, CD3+CD8+, CD3+, CD19+ and CD3-CD56+ lymphocyte percentages and absolute counts in peripheral whole blood. Absolute counts may be determined by the Navios flow cytometer using Flow-Count Fluorospheres (single platform technology method) or separate hematology results (dual platform method). It is indicated for use in the immunologic assessment of patients having or suspected of having immune deficiency.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130373

Device Name
Flow-Set™ Pro Fluorospheres

Indications for Use *(Describe)*

Flow-Set Pro Fluorospheres is a suspension of fluorescent microspheres used as an aid in standardizing forward scatter, side scatter, and fluorescence detectors (FL1-4) on the Cytomics FC 500 and Navios Flow Cytometers.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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